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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/698,121	10/30/00	AUCOUTURIER J	746200-00006

021967
HUNTON AND WILLIAMS
1900 K STREET N W
WASHINGTON DC 20006

HM12/0802

EXAMINER	
EWOLDT, G	
ART UNIT	PAPER NUMBER
1644	7

DATE MAILED: 08/02/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/698,121	Aucouturier et al.
Examiner	**Art Unit**
G. R. Ewoldt	1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Mar 2, 2001* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *1-32* are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

1. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-15, 17-18, 21-27, and 29 drawn to a composition comprising an antigen and an adjuvant, or surfactant, or combination of surfactants, classified in Class 424, subclass 185.1+.

II. Claims 1-15, 17-18, 21-27, and 29 drawn to a composition comprising an *in vivo* generator of a compound comprising an amino acid sequence, and an adjuvant, or surfactant, or combination of surfactants, classified in Class 424, subclass 185.1+ and Class 435, subclasses 91.1+ and 320.1.

III. Claims 1, 16, and 28 drawn to a composition comprising an antigen and an adjuvant, or surfactant, or combination of surfactants, and a sympathomimetic, classified in Class 424, subclass 185.1+.

IV. Claims 1, 16, and 28 drawn to a composition comprising an *in vivo* generator of a compound comprising an amino acid sequence, and an adjuvant, or surfactant, or combination of surfactants, and a sympathomimetic, classified in Class 424, subclass 185.1+ and Class 435, subclasses 91.1+ and 320.1.

V. Claims 19-20 and 30-32 drawn to a method of providing an adjuvant effect comprising a composition comprising an antigen and an adjuvant, or surfactant, or combination of surfactants, classified in Class 424, subclass 185.1+.

VI. Claims 19-20 and 30-32 drawn to a method of providing an adjuvant effect comprising a composition comprising an *in vivo* generator of a compound comprising an amino acid sequence and an adjuvant, or surfactant, or combination of surfactants, classified in Class 424, subclass 185.1+.

The inventions are distinct, each from the other because:

2. Groups V and VI are different methods. These inventions comprise different reagents acting through different process steps. Methods of vaccinating with an antigen comprise a significantly different field of search than do methods of vaccinating with "an *in vivo* generator of a compound comprising

an amino acid sequence" (i.e., a nucleic acid). Therefore, the methods are patentably distinct.

3. Inventions I-IV and V-VI are related as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)).

In the instant case, the products as claimed can be used in materially different processes such as *in vitro* assays.

4. Invention I-IV are different products. They are distinct because they are structurally and functionally different, i.e., antigens (proteins or polysaccharides) are chemically unrelated to *in vivo* generators of a compound comprising an amino acid sequence (nucleic acids). The addition of another unrelated compound (a sympathomimetic) yields yet another patentably distinct composition. Therefore the Inventions are patentably distinct.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their divergent fields of search, restriction for examination purposes as indicated is proper.

6. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

7. Should Applicant elect either Groups I, II, V, or VI Applicant is further required under 35 U.S.C. § 121 to:

1)

A) Elect a **specific** adjuvant, or a **specific** surfactant, or a **specific** mixture of surfactants, such as one of those listed in the first table of Example 1 in the specification,

B) Elect a **specific** immunostimulant (if one is so desired),

C) Elect a **specific** water-soluble metal cation organic salt (if one s so desired),

2) List all Claims readable thereon including those subsequently added. Currently Claims 1 and 19 are generic.

8. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The different adjuvants, surfactants, or immunostimulators comprise different chemical compounds or compositions with different physiological properties and modes of action. The different water-soluble metal cation organic salts likewise comprise different chemicals with different properties. Therefore, the species of Groups I, II, V, and VI, are independent and patentable over one another.

9. Any inquiry concerning this communication from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-9805. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973.

G.R. Ewoldt, Ph.D.
Patent Examiner
Technology Center 1600
July 29, 2001

Patrick J. Nolan, Ph.D.
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